

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:1957

ANSWERED ON:14.03.2017

Import of Medical Devices

Patel Shri Prahlad Singh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether India imports substantial medical devices into the country and the middle men and hospitals charge hefty amounts from poor patients and if so, the reaction of the Government thereto;
- (b) whether the Government proposes to bring a uniform pricing method for medical devices and drugs across the country and if so, the details thereof;
- (c) whether the Government is considering to publish the prices of medical devices and drug in order to bring transparency in the pricing system in the country online; and
- (d) if so, the details thereof?

Answer

MINISTER OF STATE FOR CHEMICALS & FERTILIZERS, ROAD TRANSPORT & HIGHWAYS AND SHIPPING (SHRI MANSUKH L. MANDAVIYA)

(a): As per industry estimates, India imports more than 75% of total medical devices demand. National Pharmaceuticals Pricing Authority (NPPA) vide notification no. S.O. 412(E) dated 13.02.2017 has fixed the ceiling prices of coronary stents under two categories i.e. Bare Metal Stent at INR 7260 per unit and Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents at INR 29600 per unit.

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(b): National Pharmaceutical Pricing Authority (NPPA) is the regulator for the prices of drugs declared as essential under the National List of Essential Medicines (NLEM). Government controls price of only those medical devices which are declared as essential drugs. Out of 23 Medical Devices regulated as "Drugs" under Drugs & Cosmetics Act & Rules thereunder, three devices namely 'Condom', 'IUD containing copper' & 'Coronary Stents' have been included in the Schedule-I of the Drugs (Price Control) Order, 2013 (DPCO, 2013) and are under price control. The remaining 20 medical devices are categorized as non-scheduled formulations under DPCO, 2013 and therefore, no price has been fixed for these non-scheduled medical devices. However, manufacturers are not allowed to increase the price of these 20 medical devices by more than 10% per annum. NPPA continuously monitors market prices of all essential medicines and medical devices.

(c & d): Department of Consumer Affairs has been advised to make industry aware of the requirements of the Legal Metrology Rules regarding printing of MRP on the package of medical devices and subsequently, to enforce the requirements through their field staff.

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